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| 10/507,511 | 02/14/2005 | Stephen R Ash | AATI-13 | 1187 |
| 53450 7590 03/17/2009 KRIEG DEVAULT LLP ONE INDIANA SQUARE SUITE 2800 INDIANAPOLIS, IN 46204-2079 | | | | |
| EXAMINER MAHYERA, TRISTAN J | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/507,511

Applicant(s)

ASH ET AL.

Examiner

TRISTAN J. MAHYERA

Art Unit

1615

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 21, 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/14/2005, 8/04/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II, Claims 15-23, in the reply filed on 2/9/2009 is acknowledged. The election of polyurethane/polycarbonate as the polymeric material and methylene blue is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

Claims 1-25 are pending. Claims 1-14, 21, 24 and 25 are withdrawn pursuant to 37 CFR 1.142(b), as being drawn to the non-elected invention. Claims 15-20 and 21-23 are examined on the merits.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date as follows:

The later-filed application must be an application for a patent for an invention, which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the

requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filled application, Application No. 60/364335, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior application fails to provide support for immersing the polymeric material in the liquid composition for a time selected to be between about one minute and about 24 hours and between about 60 minutes and about 240 minutes in claims 16 and 17. These claims are given a priority date of 3/14/2003.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15, 18-20, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by ILLNER (US 5,709,672 see PTO/SB/08).

ILLNER teaches a method of manufacturing polymeric material for a medical device comprising treating the device with gentian violet (i.e. organic dye) and/or silver nitrate (i.e. reducing agent) in an aqueous solution or alcohol solution for a time sufficient to impregnate the solution to the device then remove the device, rinse it and allow it to dry. See e.g. claims 6-10, col. 5 line 63 to col. 6 line 15 and col. 5 lines 38-39: instant claims 15, 18, 19, 22 and 23. The polymeric material is polyurethane. See e.g. claims 6-10: instant claim 20. The device is a catheter. See e.g. claim 8.

Claims 15, 16, 18-20 and 22-23 are rejected under 35 U.S.C. 102(e) as being anticipated by SHANBROM (US 6,361,786 see PTO/SB/08).

SHANBROM teaches a method of manufacturing a polymeric material for a medical device or catheter (see e.g. claims 9 and 10) whereby the device is contacted with a liquid composition (i.e. aqueous see e.g. col. 4 lines 10-12) comprising an organic dye (e.g. gentian violet or methylene blue, see claim 1) and a reducing agent (i.e. any number of the dyes are reducing agents, see e.g. col. 2 lines 47-50) for a time sufficient to impregnate the polymeric material (e.g. 30 minutes, see col. 4 lines 12-14) and the solution removed or washed away (see col. 4 lines 10-15). The 30 minutes immersing reads on claim 16. The aqueous solution reads on the aqueous composition in claim 18 and the water in claim 19. The polymeric material is polyurethane and polycarbonates. See e.g. claim 10: instant claim 20. The dye and/or the reducing agent are methylene blue and gentian violet, which reads on the dye in claim 22 and other reducing agents in claim 23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over ILLNER as applied to claims 15, 18-20, 22 and 23 above.

ILLNER teaches a method of manufacturing polymeric material for a medical device comprising treating the device with gentian violet (i.e. organic dye) and/or silver nitrate (i.e. reducing agent) in an aqueous solution or alcohol solution for a time sufficient to impregnate the solution to the device then remove the device, rinse it and allow it to dry, as described above.

ILLNER does not explicitly teach an impregnation time of between one minute and 24 hours or between 60 minutes and 240 minutes.

ILLNER does teach that in certain embodiments the device is to be exposed to the gentian violet for 72 hours, however, this is one embodiment of ILLNER and does not teach away from an immersion of about 240 minutes, which the Examiner believes would still show significant impregnation of the polymeric material albeit not at the level a longer impregnation would acquire.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over SHANBROM (US 6,361,786, see PTO-892).

SHANBROM teaches a method of manufacturing a polymeric material for a medical device or catheter (see e.g. claims 9 and 10) whereby the device is contacted with a liquid composition (i.e. aqueous see e.g. col. 4 lines 10-12) comprising an organic dye (e.g. gentian violet or methylene blue, see claim 1) and a reducing agent (i.e. any number of the dyes are reducing agents, see e.g. col. 2 lines 47-50) for a time sufficient

to impregnate the polymeric material (e.g. 30 minutes, see col. 4 lines 12-14) and the solution removed or washed away (see col. 4 lines 10-15), as taught above.

SHANBROM does not explicitly teach immersion for between 60 and 240 minutes.

SHANBROM does however teach immersion times of one minute (see col. 6 lines 6-7) and 6 hours (see col. 4 lines 66-67) and explicitly states that the immersion should be adjusted depending on the polymer to yield visible color (see e.g. col. 4 lines 55-64). This obviates the time of immersion to a skill well known in the art and thus the immersion time of 60 minutes to 240 minutes is obvious to one skilled in the art at the time of the invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15, 18, 19, 20, 22 and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-49 of copending Application No. 11/801616. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is directed to both methods of manufacturing and medical devices such as catheters whereby the method comprises contacting a polymeric material with a liquid composition including a paraben and an organic dye thereby providing an impregnated polymeric material. This differs from the instant application in that the paraben is used in addition to the dye, however, both the paraben and dye are known antimicrobial agents it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third

composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615